



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Firestone's

7-19-88

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Shaughnessy No.: 128825

Date Out of EAB: Jul 19 1988

To: George LaRocca
Product Manager 15
Registration Division (TS-767C)

From: Michael P. Firestone, Chief
Special Review Section #2
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Michael P. Firestone

THRU: Paul F. Schuda, Chief
Exposure Assessment Branch/HED (TS-769C)

Paul F. Schuda

Attached, please find the EAB review of....

Reg File/Rec #: 223,162

Chemical Name : Bifenthrin

Type Product : Insecticide/Miticide

Product Name : Talstar Total Release Insecticide Aerosol

Company Name : Whitmire

Purpose : Conduct exposure assessment for ornamental,
non-food, greenhouse use.

Date Received: 6/10/88 Action Code: 175

Date Completed: _____ EAB #(s): 80831

Monitoring Study Requested: _____ Reviewing Time: 5 days

Monitoring Study Volunteered: _____

Deferrals to: _____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

46673 168

1. CHEMICAL NAME **TALSTAR** (Biphenanthrin) *Total Release Insecticide, 6/13/88*

2. IDENTIFYING NUMBER 499-GNA	3. ACTION CODE 175	4. ACCESSION NUMBER	TO BE COMPLETED BY PM
			5. RECORD NUMBER 223, 162
			6. REFERENCE NUMBER 1
			7. DATE RECEIVED (EPA) 5-25-88
			8. STATUTORY DUE DATE
			9. PRODUCT MANAGER (PM) LaRocca / Dinelli
			10. PM TEAM NUMBER 15

14. CHECK IF APPLICABLE

☐ Public Health/Quarantine

☐ Minor Use

☐ Substitute Chemical

☐ Part of IPM

☐ Seasonal Concern

☐ Review Requires Less Than 4 Hours

TO BE COMPLETED BY PCB

11. DATE SENT TO HED/TSS
6-10-88

12. PRIORITY NUMBER
50

13. PROJECTED RETURN DATE
8-29-88

15. INSTRUCTIONS TO REVIEWER

A. HED ☐ Total Assessment - 3(c)(5)

C. ☐ BFSD

☐ Incremental Risk Assessment - 3(c)(7) and/or E.L. Johnson memo of May 12, 1977.

D. ☐ TSS/RD

E. ☐ Other

B. SPRD (Send Copy of Form to SPRD PM)

☐ Chemical Undergoing Active RPAR Review

☐ Chemical Undergoing Active Registration Standards Review

F. INSTRUCTIONS

Please conduct exposure assessment for this use.

16. RELATED ACTIONS

17. 3(c)(1)(D)

☐ Use Any or All Available Information ☐ Use Only Attached Data
☐ Use Only the Attached Data for Formulation and Any or All
☐ Available Information on the Technical or Manufacturing Chemical.

18. REVIEWS SENT TO

☐ TB

☐ EEB

☐ EF

☐ PL

☐ RCB

☐ EFB

☐ CH

☐ BFSD

19. To	TYPE OF REVIEW	NUMBER OF ACTIONS							
		Registration	Petition	EUP	SLN	Sec. 18	Inert	MNR. USE	Other
HED	TOXICOLOGY								
	ECOLOGICAL EFFECTS								
	RESIDUE CHEMISTRY								
	X ENVIRONMENTAL DATA	1							
RD/TSS	CHEMISTRY								
	EFFICACY								
	PRECAUTIONARY LABELING								
BFSD	ECONOMIC ANALYSIS								2

20. ☒ Label Submitted with Application Attached

21. ☐ Confidential Statement of Formula

22. ☐ Representative Labels Showing Accepted Uses Attached

23. ☐ Review (to be completed by HED)

24. ☐ Copies of This Completed Form for Each Branch Checked for Review.

1.0 INTRODUCTION

The Registration Division (RD) has requested that the Exposure Assessment Branch (EAB) conduct an exposure assessment for handlers of bifenthrin in greenhouses. Bifenthrin is an insecticide and a miticide that Whitmire is seeking to register. FMC manufactures the technical product for Whitmire, according to a verbal communication between the reviewer and George LaRocca.

The proposed treatment in greenhouses is for the use of one 16 oz. unit per 3000 ft² of a product named Talstar PT 1800, a total release insecticide/aerosol generator. Talstar 1800 contains 0.5% active ingredient (equivalent to 0.08 oz a.i. or 2.27 grams a.i.), bifenthrin, and 99.5% inert ingredients. According to Chris Dively (conversation of 7/13/88), there is only one permanent, registered use for the active ingredient bifenthrin. This is for Talstar 2 Emulsifiable Concentrate spray for greenhouse-grown ornamentals, trees and shrubs.

Part of the proposed label was included with this submission. The remainder of the proposed label, the supplemental directions for the total release aerosol, was obtained 7/12/88 from C. Dively. The entire proposed label is attached to this review.

The Toxicology Branch (TB) has classified bifenthrin as a Class C oncogen with a Q* of 5.4×10^{-2} (mg/kg/day)⁻¹ (See review of Byron Backus, 4/20/88).

No exposure data were submitted and EAB does not have adequate surrogate pesticide data to substitute for the needed exposure data.

2.0 EVALUATION OF COMPANY STUDY

Whitmire did not submit a study, so this is not applicable.

2.1 METHODOLOGY

Not applicable.

2.2 ANALYTICAL CHEMISTRY

Not applicable.

2.3 MIXER/LOADER AND APPLICATOR EXPOSURE

The data (proposed label) included with this submission are insufficient to permit assessment of exposure. No adequate surrogate pesticide data exist reflecting the intended fogger use of bifenthrin on greenhouse ornamentals.

3.0 PESTICIDE USE INFORMATION

EAB has requested that the Science Support Branch/Benefits and Use Division (SSB/BUD) generate a use data assessment for the proposed use on greenhouses ornamentals (See memorandum from EAB to BUD dated July 8, 1988. The SSB/BUD report, when received, will be filed for later use in future exposure calculations. Review of the use data will be completed upon receipt of both the SSB/BUD use estimates and registrant submission of unit exposure study data.

4.0 NONDIETARY EXPOSURE TO PESTICIDE

No exposure data were submitted by Whitmire for applicators handling the total release aerosol.

4.1 GREENHOUSES

No data reflecting applicator exposure were submitted.

5.0 CONCLUSIONS

Whitmire is requesting the registration of bifenthrin for use as an insecticide and miticide on greenhouse ornamentals. TB has classified this pesticide as a Class C oncogen. No study for applicator exposure was submitted. In addition, no adequate surrogate data are available to evaluate exposure resulting from the proposed use of bifenthrin.

For additional consideration, the petitioner should submit a protocol for a exposure monitoring study. This protocol should be reviewed and accepted by EAB prior to actual exposure monitoring. Potential dermal and/or inhalation exposure during application and post-application at appropriate reentry intervals should be measured using personal monitoring techniques approved by the Agency. See Pesticide Assessment Guidelines-Subdivision U-Applicator Exposure Monitoring for reference. Subdivision K-Reentry Protection Exposure Data Requirements would also be a helpful reference for developing the protocol.

The protocol should insure that monitoring will be done separately for each task, even if the same individual may perform more than one task. At least 15 replicates should be performed for each exposure scenario (5 at each of 3 different locations). "Replicate" means here that monitoring will be conducted of total exposure over the course of application. For the case of post-application exposure or "reentry" exposure, "replicate" means monitoring over sufficient time to establish a decay constant for bifenthrin surface residues and air concentrations.

The submitted protocol should ensure that all precautionary statements on the label must be followed during the monitoring. Because this compound contains a Class C oncogen, the protocol should provide for additional protection of exposed personnel. Additional personal

protection should be included in the protocol for the exposed experimenters, beyond the requirements of the proposed label. Individuals exposed post-application should also be required to use additional protective clothing. The registrant may consider using patches reflective of protective clothing.

All quality assurance considerations for both sampling and subsequent laboratory analyses must be discussed in the protocol approved by the Agency.

The monitoring should be conducted at or above the proposed use rate and according to the directions on the proposed label.



Linda L. Kutney
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

BIPENTHRIN

Page _____ is not included in this copy.

Pages 6 through 8 are not included.

The material not included contains the following type of information:

- _____ Identity of product inert ingredients.
 - _____ Identity of product impurities.
 - _____ Description of the product manufacturing process.
 - _____ Description of quality control procedures.
 - _____ Identity of the source of product ingredients.
 - _____ Sales or other commercial/financial information.
 - ☒ A draft product label.
 - _____ The product confidential statement of formula.
 - _____ Information about a pending registration action.
 - _____ FIFRA registration data.
 - _____ The document is a duplicate of page(s) _____.
 - _____ The document is not responsive to the request.
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Code 805

Talstar® 2 EC

Insecticide/Miticide

EPA Reg. No. 279-3056

EPA Est. 279-

Active Ingredient:

By Wt.

Bifenthrin, (2 methyl[1,1'-biphenyl]-3-yl) methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2- dimethylcyclopropanecarboxylate*	25.1%
Inert Ingredients:	74.9%
	100.0%

*Cis isomers 97% minimum, trans isomers 3% maximum.
This product contains 2 pounds active ingredient per gallon.
U.S. Patent No. 4,238,505

KEEP OUT OF REACH OF CHILDREN WARNING

STATEMENT OF PRACTICAL TREATMENT

If swallowed: Get medical attention. Call a Poison Control Center or physician promptly for advice. Describe Precautionary Statements and Notes to Physician statements on the label. Do not induce vomiting unless advised by a physician or qualified medical advisor. Do not give anything by mouth to an unconscious person.

If inhaled: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

If on skin: Wash with plenty of soap and water. Get medical attention.

If in eyes: Flush with plenty of water. Call a physician if irritation persists.

Note to Physician:

Pesticide Hotline (800) 858-7378. This product is a pyrethroid. If large amounts have been ingested, the stomach and intestine should be evacuated. Treatment is symptomatic and supportive. Digestible fats, oils, or alcohol may increase absorption and so should be avoided.

For Emergency Assistance Call 716-735-3765.

This label must be in the possession of the user at the time of application.

See other panels for additional precautionary information.

FMC®

FMC Corporation
Agricultural Chemical Group
Philadelphia PA 19103

7/87

USE Red Fr. Chn's Dively 7/13/88
ONLY REGISTERED PERMANENT USE
TO DATE / GRV USE
Net Contents

NOT REVIEWED

In accordance with PR Notice ~~82-2~~ 87-1
Based on draft labelling dated

PRECAUTIONARY STATEMENTS Hazards to Humans (and Domestic Animals)

Warning

May be fatal if swallowed or inhaled. Harmful if absorbed through skin. Causes moderate eye irritation. Do not breathe vapor or spray mist. Avoid contact with skin, eyes or clothing. Wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health. Remove contaminated clothing and wash before reuse. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Do not apply directly to water. Drift and runoff from treated areas may be hazardous to fish in adjacent sites. Do not contaminate water by cleaning of equipment or disposal of wastes.

PHYSICAL/CHEMICAL HAZARDS

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product through any type of irrigation system.

STORAGE AND DISPOSAL

Pesticide Storage

Do not freeze. Do not store below 40° F. If solid crystals are observed, warm material to above 60° F by placing container in warm location. Shake or roll container periodically to redissolve solids.

Keep out of reach of children and animals. Store in original containers only. Store in a cool, dry place and avoid excess heat. Carefully open containers. After partial use, replace lids and close tightly. Do not put concentrate or dilute material into food or drink containers. Do not contaminate other pesticides, fertilizers, water, food, or feed by storage or disposal.

In case of spill, avoid contact, isolate area and keep out animals and unprotected persons. Confine spills. Call FMC collect: (716), 735-3765.

To confine spill: If liquid, dike surrounding area or absorb with sand, cat litter or commercial clay. If dry material, cover to prevent dispersal. Place damaged package in a holding container. Identify contents.

Pesticide Disposal

Pesticide wastes are toxic. Do not contaminate water, food or feed by storage or disposal. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. Dispose of excess or waste pesticide by use according to label directions, or contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal

Glass Container: Triple rinse (or equivalent) then dispose of in a sanitary landfill or by other approved State and local procedures.

Metal or Plastic Container: Triple rinse (or equivalent) then offer for recycling or reconditioning, or for reuse and disposal of in a sanitary landfill, or by other procedures approved by State and local authorities. Do not cut or weld metal containers.

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Talstar® 2 EC insecticide/miticide

Greenhouse Grown
Ornamentals, Trees and Shrubs

DIRECTIONS FOR USE

Pest	Rate		Comments
	lb ai/10 gal	fl oz/10 gal*	
Aphids Whiteflies Mealybugs Two-Spotted Spider Mite San Jose Scale (crawlers) California Red Scale (crawlers) Pine Needle Scale (crawlers)	0.004 to 0.01	0.26 to 0.65	Apply the specified rate as a full coverage foliar spray. Repeat as necessary to achieve control, using higher rates as pest pressure increases. Do not handle the plants until the spray has dried. Certain cultivars may be sensitive to the final spray solution. A small number of plants should be treated prior to application of the entire planting. Do not use on ferns.
Omnivorous Leafroller	0.006 to 0.015	0.4 to 1.0	
Armyworms	0.01 to 0.02	0.65 to 1.3	

*1 fl oz of Talstar 2 EC = 2 tbsp = 30 ml

Dealers Should Sell in Original Packages Only.

Terms of Sale or Use: On purchase of this product buyer and user agree to the following conditions:

Warranty: FMC makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Except as so warranted, the product is sold as is. Buyer and user assume all risk of use and/or handling and/or storage of this material when such use and/or handling and/or storage is contrary to label instructions.

Directions and Recommendations: Follow directions carefully. Timing and method of application, weather and crop conditions, mixture with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller and are assumed by the buyer at his own risk.

Use of Product: FMC's recommendations for the use of this product are based upon tests believed to be reliable. The use of this product being beyond the control of the manufacturer, no guarantee, expressed or implied, is made to the effects of such or the results to be obtained if not used in accordance with directions or established safe practice.

Damages: Buyer's or user's exclusive remedy for damages for breach of warranty or negligence shall be limited to direct damages not exceeding the purchase price paid and shall not include incidental or consequential damages.

NOT REVIEWED

In accordance with PR Notice ~~82-2~~ 87-1
Based on draft labelling dated